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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,974	02/08/2002	Lhing-Yew Li		3799

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EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,974	LI ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-23 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final Office action (mailed on February 11, 2004), Applicants filed response and amendment received on June 9, 2004. Said amendment cancelled Claim 14 and amended Claims 1-4, 6-13, 15, and 25. Thus, Claims 1-13 and 15-25 are pending in the instant Office action. Claim 24 remains withdrawn from consideration as a non-elected invention. Thus, Claims 1-13, 15-23, and 25 will be examined herein.

Priority

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/267,183 filed on February 8, 2001. The Examiner also previously noted that the provisional has support only for Claim 25 (not Claims 1-23) of the elected claims.

Applicant argues that Claim 2 is supported in the provisional application (60/267,183) in paragraph [0038]; the Examiner disagrees, particularly in view of the added limitation, “at least 25% of the full length ddh”, in the pending claim. Since Claims 9 and 13 depends from Claim 2, they also lack support despite Applicant’s arguments for the reasons above.

Compliance with the Sequence Rules

3. By virtue of Applicant’s amendment citing SEQ ID NOs in Figure 10 and on page 29, the instant application now fully complies with the sequence rules.

Withdrawn - Objections to the Specification

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.
5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.
6. Previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicant's amendment.

Withdrawn - Objections to the Claims

7. Previous objection to Claims 7-11 for a typographical error is withdrawn by virtue of Applicant's amendment.

Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

8. Previous rejection of Claims 1-23 and 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for abbreviations dapB, lysA, dapA, dapD, dapE and dapF is withdrawn by virtue of Applicant's amendment.
9. Previous rejection of Claims 2-6, 9-11, and 13-15 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "truncated" is withdrawn by virtue of Applicant's amendment.

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10. Previous rejection of Claims 3-6, 10, 11, 14, and 15 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “ORF2” polypeptide is withdrawn by virtue of Applicant’s amendment to include specification structural limitations on the term.

11. Previous rejection of Claims 7 and 9-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “encoded by *Corynebacterium* ...” is withdrawn by virtue of Applicant’s amendment.

12. Previous rejection of Claim 8 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “wherein said ask and asd polypeptides are encoded by the ask-asd operon of ATCC21529” is withdrawn by virtue of Applicant’s amendment.

13. Previous rejection of Claims 7 and 9-11 under 35 U.S.C. § 112, second paragraph, as being indefinite for the Group of “*Corynebacterium*, *Brevibacterium flavum*, and *Brevibacterium lactofermentum*” is withdrawn by virtue of Applicant’s amendment.

Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

14. Previous rejection of Claim 20 under 35 U.S.C. § 112, second paragraph, as being indefinite for the inclusion of *Brevibacterium lactofermentum* and *Corynebacterium glutamicum* in the Group is maintained and amended to herein include Claims 26-29 for the same reasons. Applicant’s arguments have been fully considered but are not deemed persuasive.

Applicant first notes that the art “may indicate” that these are the same species; this is exactly the Examiner’s point as to why the three species cannot be together in a Markush group -

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because the Markush group would contain three identical members and would be confusing as such. This idea is supported by the art cited by Applicant where, in the Abstract, it reads “*B. divaricatum* ..., *B. flavum* ..., *B. lactofermentum* ..., *C. lilum* ..., and *C. glutamicum* ...are **members of the same species** (emphasis added).

Additionally Applicant argues that the reference Liebl *et al.* (Int’l J Systemic Bacteriol. (1991) 41(2): 255-260 as attached by Applicant) teaches *B. flavum*, *B. lactofermentum*, and *C. glutamicum* are different, specifically that they are distinct strains. While this may be the case, the specific strains of Liebl *et al.* are not in the claims. What are in the Markush groups of the claims are identical species of *B. flavum*, *B. lactofermentum*, and *C. glutamicum*, and as such, the claims are confusing.

15. Previous rejection of Claim 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “N-succinylaminoketopimelate transaminase (dapC)” is maintained. Applicant’s arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the removal of “dapC” renders the term clear; the Examiner disagrees. As previously noted, the enzyme name N-succinylaminoketopimelate transaminase is not found in an enzyme database; however, the enzyme succinyldiaminopimelate transaminase (or aminotransferase) is found as E.C. 2.6.1.17. It is unclear if N-succinylaminoketopimelate transaminase is meant to have the activity of succinyldiaminopimelate transaminase or of some other enzyme. Clarification is required.

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Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

16. Previous rejection of Claims 12-15 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment so that the instant claims now include an exact structure correlating to an exact function as required by the enzyme name in the claims.

Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

17. Previous rejection of Claims 3-6, 10, 11, 14, and 15 under 35 U.S.C. § 112, first paragraph, written description, is maintained and amended to include Claims 28-29 for the same reasons. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that the structural limitation added to Claims 3 and 4 address the rejection; the Examiner disagrees. As previously noted,

“To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.”

In the instant specification, a single species of ORF2 polypeptide is described as SEQ ID NO:10. However, in the absence of functional language, the instant claims read on nucleotide sequences within the sequence identity limitations but having different function than SEQ ID NO:10. It is these sequences that are not described rendering the scope of the instant claims not described by the specification.

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18. Previous rejection of Claim 8 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the inclusion of SEQ ID NOs in the claims renders the rejection moot; the Examiner disagrees. If the SEQ ID NOs were associated with the particular activity (ask or asd), this would be the case. However, the instant claims do not require the sequence that is 95% identical to SEQ ID NO:1 to have ask activity, etc. For these reasons, the instant rejection is maintained.

Maintained - Claim Rejections - 35 U.S.C. § 102

19. Previous rejection of Claims 1-13, and 15-23 under 35 U.S.C. § 102 as being anticipated by Li *et al.* (WO 01/49854 – see IDS) is maintained but amended to be under section (a) of the statute. Applicant's arguments, in both the "Priority" and the Art Rejection sections, have been fully considered but are not deemed persuasive for the following reasons.

Applicant argues that WO 01/49854 is not available under 35 U.S.C. § 102(e) because the WO document does not designate the US; this is the case. However, due to the lack of granting of priority to Claims 1-13 and 15-23 to the provisional document 60/267,183 (see answers to arguments above in Priority section), WO 01/49854 is available under 35 U.S.C. § 102(a) as of its publication date of July 12, 2001, which is prior to the filing date of the instant application of February 8, 2002 by less than a year.

20. Previous provisional rejection of Claims 1-4, 7-13, 15-18 and 20-21 under 35 U.S.C. 102(e) as being anticipated by Hanke *et al.* (U.S. Application 09/722,441, now allowed) is maintained. Applicant's arguments have been fully considered but are not deemed persuasive.

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Applicant argues that the declaration by inventor Lhing-Yew Li under 35 U.S.C. § 1.132 obviates the rejection; the Examiner disagrees because the declaration is unclear as to what exactly was invented by inventor Li in both 09/722,441 and in the instant application. The subject matter of “conception, design, and construction of the gene cassettes” seems to be the entirety of the subject matter of the claims of 09/722,441 and the instant application as both sets of claims are drawn to genes cassettes. Moreover, inventor Li writes “I was the sole inventor of that subject matter”, which, if the Examiner’s assessment of “that subject matter” is correct, is the entirety of the claims of both applications and raises concerns of inventorship for both applications. The statute reads:

A person shall be entitled to a patent unless –

(e) the invention was **described in a patent** granted on an application for patent **by another filed in the United States** before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent. (emphasis added)

In the instant case, the prior art is allowed patent application 09/722,441 filed by Hanke, Li-D-Elia, Walsh, Crafton, and Rayapati (5 inventors) and the instant application is filed by Li and Trei (2 inventors), thus the inventive entity is different and the prior art is “by another”.

As previously noted, “allowed claims of 09/722,441 are species of some claimed genera in the claims of the instant application as follows:

<u>Allowed claims of 09/722,441</u>	<u>Pending claims of 10/067,974</u>
21	1-4 and 7-15
24-25	16
26	17
27	18, 20
28	21

The species allowed in 09/722,441 anticipate the genus claimed in 10/067,974.”

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Withdrawn - Double Patenting

21. Previous rejection of Claims 1-4, 7-18 and 20-21 under the judicially created doctrine of double patenting over claims 21 and 24-28 of copending Application No. 09/722,441 is withdrawn by virtue of Applicant's filing of a terminal disclaimer.

The terminal disclaimer filed on June 9, 2004 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of 09/722,441 has been reviewed and is accepted. The terminal disclaimer has been recorded.

NEW ISSUES

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

22. Claims 2, 4-6, 9, 11, 13, 15, 27, and 29 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Defining a truncated ddh (or diaminopimelate decarboxylase) polypeptide as having at least 25% of the full length of a ddh polypeptide (or diaminopimelate decarboxylase) is considered new matter. The support cited in Applicant's arguments filed on June 9, 2004 cite paragraph [0066], which describes truncations

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of ORF2 polypeptides and not generic truncations of any of the polypeptides of the invention.

Applicant must remove the new matter or cite clear support for the alleged new matter in the specification as originally filed.

23. Claims 2, 4-6, 9, 11, 13, 15, 27 and 29 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2 and 4 are drawn to polynucleotides comprising truncated ddh or diaminopimelate decarboxylase that is claimed with neither structural nor functional limitations.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

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In the instant specification, full-length genes encoding ddh and diaminopimelate decarboxylase are described. The structure of these genera of enzymes is defined, in the art, by virtue of its enzyme name and correlated activity. However, when the enzyme is “truncated” and without an enzymatic function stipulation in the claims, the structure/function of the name of the enzyme no longer garners a specific structure/function of the polynucleotide in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure.

24. Claims 7, 9-11, and 26-29 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant rejection is based on the limitation of being “native to ... *Corynebacterium*”.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

In the specification, a single example of an ask, ddh, ORF2, and lysA from coryneform that meets the limitations of the instant claims is described. No examples of other coryneform sequences are described, either ask, ddh, ORF2, and lysA sequences or general coryneform sequences. The instant claims are drawn to a *subgenus* of all ask, ddh, ORF2, and lysA genes

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within the claimed structural limitations, wherein the DNA must be from coryneform. The specification does not describe coryneform ask, ddh, ORF2, and lysA sequences to the exclusion of ask, ddh, ORF2, and lysA sequences from other sources. Clearly, ask, ddh, ORF2, and lysA sequences from coryneform within the structural limitations are enabled by the disclosure; however, one of skill in the art would be unable to recognize other members of the claimed subgenus to the exclusion of, for example, ask, ddh, ORF2, and lysA genes from *E. coli*, within the structural limitations. Thus, the claimed subgenus does not have adequate written description.

Conclusion

25. Claims 1-13, 15-23 and 25 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

September 1, 2004